Protocol Name/Code: Comparative Evaluation of External Chest Wall Fixator Treatment Effectiveness in Patients With Rib Fractures

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1. SUMMARY OF THE STUDY
Within the scope of the research, an experimental group of 14 people and a control group of 20 people will be determined. The "Chrisofix External Fixator" fixation orthosis will be applied externally to the rib rib-fracture area along with standard medical treatment to the experimental group, and standard treatment-medical treatment will be applied to the control group. Within the scope of the research, treatment times, difference between initial pain levels and discharge pain levels, and return to work times between these groups will be compared. It is expected that the Chrisofix External Fixator applied as a result of the project will shorten the treatment time, reduce pain and accelerate the return to work process.

2. JUSTIFICATION AND OBJECTIVES OF THE STUDY
Introduction and Rationale of the Study:
The aim of the study is to shorten the recovery time in rib fracture cases with external fixation treatment, increase comfort, reduce pain level, provide a significant decrease in the time it takes for patients to return to daily life, and reduce rib fracture-related complications in patients.
Main Purpose of the Study
The aim of the study is to shorten the recovery time in rib fracture cases with external fixation treatment, increase comfort, reduce pain level, provide a significant decrease in the time it takes for patients to return to daily life, and reduce rib fracture-related complications in patients.
Secondary Purpose of the Study

3. HYPOTHESIS OF THE STUDY
1)External fixation reduces the pain level in cases with rib fractures 2) External fixation shortens the hospital stay in cases with rib fractures 2) External fixation reduces the development of complications in cases with rib fractures

4. POPULATION TO BE RESEARCHED & SELECTION OF VOLUNTEERS

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Disease Name	Rib fracture			
Number of Volunteers and Characteristics		**Kadın**	**Erkek**	**Yaş aralığı**
	Sağlıklı :	**0**	**0**	**-**
	Hasta (Hastalığın adı) :	**15**	**15**	**20-50**
	Toplam sayı :	**15**	**15**	**20-50**

Regulations Regarding the Participation of Volunteers in the Study

Volunteers will consist of patients who applied to Ege University Faculty of Medicine Hospital after trauma and were admitted to the Thoracic Surgery service and who agreed to participate in the study.

Criteria for Inclusion in the Study

- Patients with serial rib fractures after trauma
- Patients without extrathoracic pathology

Criteria for Exclusion from the Study

- Patients with less than 3 rib fractures
- Patients with extrathoracic injuries
- Patients with bilateral rib fractures
- Patients with flail chest
- Patients with hemothorax or pneumothorax requiring drainage with tube thoracostomy at first admission

Criteria for Exclusion from the Study and Procedures to be Followed in This Case

Volunteers can leave the study at any stage of the study. Volunteers who have problems completing any of the study steps may be excluded from the study. Follow-up of individuals who withdraw or are excluded from the study will continue as should be in routine practice.

5. STUDY DESIGN & METHOD

Study Design

Patients who were admitted due to trauma and had serial rib fractures were evaluated. There were 14 patients in case group and 20 in control group.

Details of Working Method

Standard treatment was applied to the control group. External chest wall fixator was applied to the case group in addition to standard treatment. Pain levels of the patients, development of complications and duration of hospitalization were recorded. Pain levels of the patients were evaluated using the Visual Analogue Scale and the pain level was scored between 0 and 10.

Defining Transactions During Working Days & Visits

The patient's pain level will be recorded using the Visual Analogue Pain Scale during visits on the day of admission and the day of discharge.

Randomization Method and Its Importance (if any)

None

Blindness Method & Importance (if any)

Date/ Version: 11.06.2020

None

Ensuring Patient Compliance

Patients will be informed by us when they are admitted to the Thoracic Surgery service, they will be asked if they want to participate in the study, and if they want to participate, they will have to sign an informed consent form. If the patient does not want to participate in the study, he will be hospitalized again and standard medical treatment for rib fracture will be applied.

Materials to be Used & Storage Conditions & Responsibilities

6. COLLECTION OF STUDY DATA

Recording Data/Case Report Forms

The data of the patients will be recorded with case report forms during the days they stay in the thoracic surgery service.

Interpretation and Reporting Methods

Visual Analog Scale (VAS) will be used to determine the pain level of the patients.

Evaluation Criteria

Number/location of rib fractures
unclassified incident
Accident Type
Pathology accompanying rib fracture
Pain level on the 10th day
1st month pain level
3rd month pain level
development of complications
Length of hospital stay

7. SURGICAL PROCEDURES (if applicable)

None

8. PRECAUTIONS & WARNINGS TO ENSURE VOLUNTEER SAFETY

9. CONDITIONS WHICH MAY REQUIRE SUSPENSION OF OPERATION

10. STATISTICAL PROCEDURES

Sample Size

34

Statistical and Analytical Methods

For categorical variables in descriptive analyses; number and percentage values for continuous variables; Mean, standard deviation, min-max and range values will be presented.

Kolmogorov-Smirnov and Shapiro Wilk tests will be performed to examine compliance with normal distribution. Chi-square, Mann Whitney U test and Spearman rank correlation will be used to examine the statistical relationship between groups.

Statistical significance level will be determined as $p<0.05$.

11. ETHICAL AND LEGAL REQUIREMENTS & PROVIDING QUALITY ASSURANCE
Good Clinical Practices and Good Laboratory Practices & Declaration of Helsinki
Responsible and assistant researchers will adhere to the principles of the "Declaration of Helsinki" throughout the study. The study will be conducted according to the principles outlined in good clinical practice.
Informing Patients and Informed Volunteer Consent
Informed consent form was obtained from each patient to be included in the study.
Ensuring Privacy
Responsible and co-investigators will keep patient names confidential and protect patients' identities from unauthorized persons. Only the name and surname initials of the patients will be written on the case report form. Any documentation required to identify the patient will be kept in strict confidence by the researcher. In accordance with Good Clinical Practice and legal requirements, the principal investigator will allow the appropriate authority(ies) to review patients' files.
Protocol Changes and Approval of Changes
Before any changes to the protocol are implemented, approval will be obtained from the local ethics committee for any regulations that may affect the safety of patients or the conduct of the study. Situations where the change is necessary to eliminate an immediate risk or where the change involves only logistical or administrative aspects (e.g. change in Monitor(s), change of telephone number) will be excluded from this scope.
Informing the Local Ethics Committee
This protocol will be submitted to the Local Ethics Committee by the principal investigator. Before the study is initiated, a document stating the date on which the Local Ethics Committee met and the approval was received will be documented and given to the researcher. After obtaining approval from the local ethics committee, any changes made to the protocol will be submitted to the Ethics Committee by the researcher in accordance with local procedures and regulatory requirements. The investigator will report all adverse and serious adverse events to the local ethics committee and will comply with any requirements to submit an annual report and any additional local reporting.
Records Retention and Quality Assurance Measures
The investigator will maintain adequate and accurate records so that the conduct of the study can be fully documented and study data can be subsequently verified. These documents should be classified into two separate categories: 1) The investigator's study file and 2) The patient's clinical source documents. The investigator's study file includes protocols/amendments, Local Ethics Committee and regulatory authority approval and correspondence, a sample informed consent, medication records, personnel CVs and authorization documents, and other appropriate documents/correspondence, etc. will be found. Additionally, at the end of the study, the investigator will keep the patient data on a CD in human-readable format, including all changes in the data, correspondence to resolve questions, and an audit string containing the reasons for the changes, which will be stored in the investigator's study file. Patient's clinical source documents (these are usually pre-defined in the project to record key efficacy/safety parameters that are independent of the Case report forms) patient hospital/clinic records, physician's and nurse's notes, appointment book, original laboratory reports, ECG, EEG, X-ray, pathology and special It will include examination reports, signed informed consent forms, consultation reports and logbooks. The investigator will retain these two types of documents for at least 15 years after completion or discontinuation of the study. After this time period, documents may be destroyed in accordance with local regulations.
Financial and Criminal Liability

In case of deviation from the protocol of the study, financial and criminal liability belongs to the responsible researcher.

12. MONITORING AND SUPERVISING THE WORK

13. REFERENCES

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2) Lee Y, Lee SH, Kim C, Choi HJ. Comparison of the effectiveness in pain reduction and pulmonary function between a rib splint constructed in the ER and a manufactured rib splint. Medicine (Baltimore) 2018 May;97(21):e10779

3) Liebsch C, Seiffert T, Vlcek M, Beer M, Huber-Lang M, Wilke HJ. Patterns of serial rib fractures after blunt chest trauma: An analysis of 380 cases. PLoS One. 2019 Dec 19;14(12):e0224105.

4)Sirmali M[1], Türüt H, Topçu S, Gülhan E, Yazici U, Kaya S et all. A comprehensive analysis of traumatic rib fractures: morbidity, mortality and management. Eur J Cardiothorac Surg. 2003 Jul;24(1):133-8.

5)Lin FC, Li RY, Tung YW, Jeng KC, Tsai SC. Morbidity, mortality, associated injuries, and management of traumatic rib fractures. J Chin Med Assoc. 2016 Jun;79(6):329-34.

6)Ziegler DW., Agarwal NN. The morbidity and mortality of rib fractures. The Journal of Trauma**,** 01 Dec 1994, 37(6):975-979

Date / Signature

RESPONSIBLE RESEARCHER